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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,656	03/06/2002	Nelson Canter	U-Wp-5597	8534
7590 10/17/2003 WILLIAM R. MORAN 333 East 43rd Street New York, NY 10017			EXAMINER LEARY, LOUISE N	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,656	CANTER ET AL.	
	Examiner	Art Unit	
	Louise N. Leary	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-9,12-16,19-20 is/are rejected.
- 7) ☒ Claim(s) 6,7,10,11,17 and 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

1. Claims 1-20 are pending in this application.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, 12-16 and 19-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zimmerle (US 5,403,744).

Zimmerle discloses a test device for determining specific gravity (SG) of a urine sample which measures the concentrating and diluting abilities of the kidneys of an individual. See column 1, lines 12-27 and lines 45-49. The test device Zimmerle discloses is suited for "...performing specific gravity assays outside a medical office or laboratory." Note column 3, lines 34-36. Zimmerle addresses determining dehydration in a human by disclosing "[Urine specific gravity likewise is elevated when an individual has lost an excessive amount of water, such as with sweating, fever, vomiting and diarrhea.]" See column 2, lines 9-12. Regarding the SG ranges set forth in the instant

claims, Zimmerle discloses “the specific gravity of urine ranges from about 1.005 to about 1.030, and usually is in the range from about 1.010 to about 1.025. A specific gravity of about 1.025 or above in a random first morning urine specimen indicates a normal concentrating ability of the kidneys.” Note column 1, lines 49-53. In regards to the color transitions described in the instant claims, Zimmerle discloses “A specific gravity reading of about 1.005 to about 1.030 is signified by color transitions, from blue-green through green to yellow-green, that serve as reliable indicators of increasing specific gravity.” Note column 4, lines 10-21. With respect to the description of the first and second portions of the instant article, Zimmerle discloses the SG strips are sample dependent, “...and comprise a carrier matrix impregnated with a reagent composition including a polyelectrolyte, such as a partially neutralized poly(methyl vinyl ether/maleic acid); a chromogenic indicator, such as bromothymol blue; and suitable buffering agents.” See column 3, lines 51-56. With respect to the instant claim limitation “...the elongated member is composed at least in part of plastic”, Zimmerle discloses “...the test strip includes a support strip, or handle normally constructed from a hydrophobic plastic, and a reagent test pad...” Note column 23, lines 38-50. Further, regarding the instant claim limitation “...the elongated member is composed at least in part of plastic polyethylene”. See column 24, lines 17-21. Thus, Zimmerle discloses the invention claimed except for stating “the human is one engaged in athletic activities.”

However, with respect to the instant claim limitation “the human is one engaged in athletic activities”, Zimmerle discloses “[Urine specific gravity likewise is elevated when an individual has lost an excessive amount of water, such as with sweating, fever,

vomiting and diarrhea.]” whereby the disclosure provided sufficient guidance for skilled as well as unskilled artisans to use the device for self-determination of the hydration state of a human engaged in athletic activities. Hence, Zimmerle discloses all the limitations of the invention claimed except for implicitly stating the device was used for self-determination of the hydration state of a human engaged in athletic activities which is deemed to be an inherent property of the device and the use of the device by a human engaged in athletic activities was implied by the Zimmerle disclosure which anticipates or renders obvious the claimed invention.

Therefore, the burden of proof is on applicants to show patentably distinct differences between the Zimmerle disclosure and the invention claimed herein.

3. Claims 6-7, 10-11, and 17-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The Falb et al reference (US 4,318,709) has been cited to further show the state of this art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone

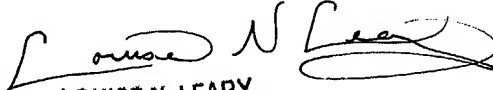
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number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

October 15, 2003